1639

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

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WRITER'S DIRECT NUMBER:
(202) 772-8697
INTERNET ADDRESS:
TMULLER@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1639

Re: U.S. Utility Patent Application
Application No. 10/052,942; Filed: January 23, 2002
For: **Methods of Producing or Identifying Intrabodies in Eukaryotic Cells**
Inventors: ZAUDERER *et al.*
Our Ref: 1821.0090004/EJH/T-M

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Substitute Restriction and Election of Species Requirements; and

2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Tracy L. Muller
Attorney for Applicants
Registration No. 55,472

EJH/T-M/nef
Enclosures

331772_1.DOC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
ZAUDERER *et al.*
Appl. No.: 10/052,942
Filed: January 23, 2002
For: **Methods of Producing or Identifying Intrabodies in Eukaryotic Cells**

Confirmation No.: 1028
Art Unit: 1639
Examiner: Epperson, J.D.
Atty. Docket: 1821.0090004/EKS/EJH/T-M

Reply to Substitute Restriction and Election of Species Requirements

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated **October 7, 2004**, requesting an election of one group of claims to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1-45, 48-65 and 69-80. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to pursue the non-elected claims in one or more divisional applications.

This election is made **with** traverse.

With respect to the Examiner's division of the claims into five groups and the reasons stated therefor, Applicants respectfully traverse. Each of the groups is related. For example, Groups I and II are related as between a method of selecting polynucleotides which encode an intracellular immunoglobulin molecule from libraries of polynucleotides and a method of producing the libraries of polynucleotides. Likewise, Groups I and III are related as between method of selecting polynucleotides which

encode an intracellular immunoglobulin molecule and a kit for the identification of an intracellular immunoglobulin molecule. Groups I, IV, and V are related as between a method, an intracellular immunoglobulin produced by that method, and a composition comprising the intracellular immunoglobulin produced by the method. Furthermore, all of the claims can be examined without serious burden on the Examiner because a search of the art for the claims of Group I should find art relevant to the claims of any other groups. For example, Groups I, II, and III are grouped in the same class for search purposes. Therefore, fewer restriction groups should expedite prosecution without an undue burden on the Examiner.

Even assuming, *arguendo*, that Groups I-V represent distinct or independent inventions, Applicants submit that to search and examine the subject matter of these Groups together would not be a serious burden on the Examiner. In particular, any art related to a method of selecting polynucleotides which encode an intracellular immunoglobulin molecule, as in Group I, is very likely to overlap substantially with art related to a kit for identification of an intracellular immunoglobulin molecule, as in Group III. Likewise, art related to a method of selecting polynucleotides which encode an intracellular immunoglobulin molecule (Group I) is very likely to overlap substantially with art related to an intracellular immunoglobulin produced by that method (Group IV), and a composition comprising an intracellular immunoglobulin and a pharmaceutically acceptable carrier (Group V). Accordingly, it would not be an undue burden for the Examiner to search, at a minimum, Groups I, IV, and V together. The M.P.E.P. § 803 (8th ed., Aug. 2001, Rev. May 2004) states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of the M.P.E.P. § 803, Applicants respectfully request that all claims be searched and examined in the subject application. Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

The Examiner has also required numerous species elections. Applicants' provisional elections are listed below, along with a listing of each of the claims believed to read on each of the provisionally-elected species.

These elections are made **with** traverse.

Subgroup 1. The Examiner has required an election of species among host cells. Applicants hereby provisionally elect to prosecute the species comprising HeLa cells that are permissive for the production of infectious virus particles. Applicants believe that claims 1-84 read on the provisionally elected species.

Subgroup 2. The Examiner has required an election of species among immunoglobulin sources. Applicants hereby provisionally elect to prosecute the species comprising a human as the source of immunoglobulin. Applicants believe that claims 1-84 read on the provisionally elected species.

Subgroup 3. The Examiner has required an election of species among intracellular immunoglobulins for "first" and "second" libraries. Applicants hereby provisionally elect to prosecute the species comprising IgG, which is not single chain, for

both first and second libraries. The Examiner has also indicated that Applicants should include the "physical makeup" of the elected immunoglobulin species, and referred by way of example to "figure 13a wherein VH-CH1-TM-DD." (Office Action at page 6.) Applicants respectfully point out that there is no "figure 13a" in the captioned application. Out of the utmost caution in being fully responsive, however, Applicants further specify that the provisionally elected species is a full IgG molecule that is soluble (as opposed to membrane-bound). If this is the incorrect interpretation of what the Examiner requires with respect to "physical makeup," Applicants respectfully request clarification. Applicants believe that claims 1-68 read on the provisionally elected species.

Subgroup 4. The Examiner has required an election of species among "first" and "second" library construction. Applicants hereby provisionally elect to prosecute the species comprising a vaccinia virus vector, which is an animal virus vector, for both first and second libraries, wherein the genome is linear, double-stranded DNA, and which is not attenuated and not deficient in D4R synthesis. Applicants believe that claims 1-20, 22, 24-27, 29-35, 38, and 40-84 read on the provisionally elected species.

Subgroup 5. The Examiner has required an election of species among promoters. Applicants hereby provisionally elect to prosecute the species comprising a T7 phage promoter which is constitutive and which is not a synthetic early/late promoter. Applicants respectfully point out that the Examiner appears to be referring to two different promoters which control two different functions in this subgroup. In particular, the last two features set forth by the Examiner (*i.e.*, whether or not said promoter is associated with a suicide gene, and how a nonconstitutive promoter is regulated or

induced) relate to the exhibition of a modified phenotype (as opposed to a promoter in operable association with polynucleotides encoding subunit polypeptides). Out of the utmost caution in being fully responsive, Applicants further specify that the provisionally elected species comprising a constitutive T7 phage promoter is not associated with a suicide gene. However, if this is the incorrect interpretation of what the Examiner requires with respect to this election, Applicants respectfully request clarification. Applicants believe that claims 1-41, 44, 46-49, 52, and 57-84 read on the provisionally elected species.

Subgroup 6. The Examiner has required an election of species among transcriptional control regions. Applicants hereby provisionally elect to prosecute the species comprising a T7 phage promoter that is active in cells in which T7 RNA polymerase is expressed, which functions in the cytoplasm, and which is not a transcriptional termination region. Applicants believe that claims 1-41, 44, and 46-84 read on the provisionally elected species.

Subgroup 7. The Examiner has required an election of species among modified phenotypes. Applicants hereby provisionally elect to prosecute the species comprising cell death caused by expression of a suicide gene. Applicants believe that claims 1-48, 50-52, and 59-84 read on the provisionally elected species.

Subgroup 8. The Examiner has required an election of species among heterologous peptides. Applicants hereby provisionally elect to prosecute the species comprising SV40 large T antigen nuclear localization signal. Applicants believe that claims 1-62 and 66-84 read on the provisionally elected species.

Applicants respectfully traverse and request the withdrawal of the requirement for election of species. On page 4 of the Office Action, the Examiner asserts that the claims are directed to patentably distinct species. However, as a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – §806.05(i)).
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> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the subgroups listed by the Examiner represent patentably distinct species, restriction remains improper unless it can be shown that the search and examination of the listed groups would entail a "serious burden." *See* M.P.E.P. § 803. In the present situation, no such showing has been made. For example, although the Examiner has asserted that embodiments referring to intracellular immunoglobulins, Applicants submit that a search of IgG as a species intracellular immunoglobulin would provide useful information regarding other types of immunoglobulins, such as IgM. Thus, the search and examination of all species would not entail a serious burden.

Applicants assert the right to have additional species examined in the event that a generic claim is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

Reconsideration and withdrawal of the Requirement for Election of Species, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Tracy L. Muller
Attorney for Applicants
Registration No. 55,472

Date: November 8, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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